

## Immunization Protocol

<b>Varicella-Zoster Immune Globulin (VARIZIG®)</b>	
Last Reviewed	08 Sept 2023
Last Revised	08 Sept 2023
This order expires	30 Sept 2025

### Table of contents

1. What's new .....	1
2. Oregon immunization protocol .....	2
3. Vaccine schedule for varicella-zoster immune globulin .....	2
4. Licensed varicella-zoster immune globulin .....	3
5. Recommendations for use .....	3
6. Contraindications .....	4
7. Warnings and precautions: .....	4
8. Other considerations .....	5
9. Side effects and adverse reactions .....	5
10. Storage and handling .....	6
11. Adverse events reporting .....	6
12. References .....	6

### 1. What's new

Reformatted. Reviewed for accuracy. No substantive changes.

## 2. Oregon immunization protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications and precautions.
- C. Provide product information, answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for intramuscular (IM) injection.
- F. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.
- G. Give appropriate dose for age and exposure Intramuscularly (IM). See Section 3.
- H. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

---

Health Officer Signature

Date

---

Health Officer Signature

Date

## 3. Vaccine schedule for varicella-zoster immune globulin (VZIG)

Route: IM				
Weight of Patient		VARIZIG® Dose		Volume to Administer (mL)*
Kilograms	Pounds	IU	Number of Vials	
≤2.0	≤4.4	62.5 <sup>◇</sup>	0.5	0.6
2.1-10	4.5-22.0	125	1	1.2
10.1-20	22.1-44.0	250	2	2.4
20.1-30	44.1-66.0	375	3	3.6
30.1-40	66.1-88.0	500	4	4.8
≥40.1	≥88.1	625 <sup>§</sup>	5	6.0

\*Divide the IM dose and administer in two or more injection sites, depending on patient size. Do not exceed 3 mL volume per injection site in adults.

<sup>◇</sup>Minimum dose for small infants under two kilograms body weight.

<sup>§</sup>Maximum dose for all patients greater than 40 kilograms body weight.

## 4. Licensed VZIG

Product Name	Vaccine Components*	Presentation	Acceptable Age Range
VARIZIG®	Lyophilized powder 125 IU of anti-varicellazoster virus (VZV) 10% maltose 0.03% polysorbate 80  VARIZIG® contains less than 40 µg per mL of IgA	Sterile liquid: 125 IU of anti-VZV in a 3 mL type 1 glass tubing vial	All ages

\*Does not contain latex, thimerosal, or mercury.<sup>1</sup>

## 5. Recommendations for use

A. VZIG is indicated for post-exposure prophylaxis of varicella in high-risk individuals to reduce the severity of varicella disease and should be administered as soon as possible after exposure to varicella virus, and within 10 days, for the following populations:<sup>2</sup>

- **Immunocompromised** children and adults without evidence of immunity.
- **Newborn infants** whose mothers have signs and symptoms of varicella around the time of deliver (i.e., 5 days before to 2 days after).
- **Hospitalized premature infants** born at  $\geq 28$  weeks of gestation who are exposed during the neonatal period and whose mothers do not have evidence of immunity.
- **Hospitalized premature infants** born at  $< 28$  weeks of gestation or who weigh  $\leq 1,000$ g at birth and were exposed during the neonatal period, regardless of their mother's immunity status.
- **Pregnant women** without evidence of immunity.

B. Evidence of immunity to varicella includes any of the following<sup>3</sup>:

- **Documentation** of age-appropriate varicella vaccination;
  - Preschool-age children (i.e., age 12 months through 3 years): 1 dose
  - School-age children, adolescents or adults: 2 doses
- **Laboratory evidence** of immunity or laboratory confirmation of disease
- **Birth** in the United States before 1980 (Should be considered evidence of immunity for health care personnel, pregnant women, and immunocompromised persons)
- **Diagnosis** or verification of a history of varicella or herpes zoster by a health care provider

- **To verify a history** of varicella, health care providers should inquire about:
  - An epidemiologic link to another typical varicella case or to a laboratory confirmed case, or
  - Evidence of laboratory confirmation if testing was performed at the time of acute disease.

Persons who have neither an epidemiologic link nor laboratory confirmation of varicella should not be considered as having a valid history of disease. For these persons, a second dose of vaccine is recommended if they previously received only one dose. If a health care provider verifies the diagnosis based on the above criteria, then vaccination is not needed.

## 6. Contraindications<sup>1</sup>

- A. History of anaphylactic or severe systemic reactions to human immune globulins.
- B. IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.

## 7. Warnings and precautions<sup>2</sup>:

- A. **Thrombotic events:** Thrombotic events may occur during or following treatment with immune globulin products. Patients at risk include those with a history of atherosclerosis, multiple cardiovascular risk factors, advanced age, impaired cardiac output, coagulation disorders, prolonged periods of immobilization, and known or suspected hyperviscosity. Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity including those with cryoglobulins, fasting chylomicronemia, markedly high triacylglycerols (triglycerides), and monoclonal gammopathies.
- B. **Coagulation disorders:** Administer VARIZIG<sup>®</sup> intramuscularly only. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, only administer VARIZIG<sup>®</sup> if the expected benefits outweigh the potential risks.
- C. **Hypersensitivity:** Severe hypersensitivity reactions may occur following VARIZIG<sup>®</sup> administration. Administer VARIZIG<sup>®</sup> in a setting with appropriate equipment, medication and personnel trained in the management of hypersensitivity, anaphylaxis and shock. In the case of hypersensitivity, discontinue administration of VARIZIG<sup>®</sup> immediately and provide appropriate treatment
- D. **Infectious agents:** Because VARIZIG<sup>®</sup> is made from human plasma, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt–Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt–

Jakob disease (CJD) agent. Plasma donors are screened for the presence of certain infectious agents, and the manufacturing process for VARIZIG® includes measures to inactivate and remove certain viruses. No cases of transmission of the viral diseases, vCJD or CJD have been associated with the use of VARIZIG®. Report all infections thought by a physician to have been transmitted by VARIZIG® to Saol Therapeutics at 1-833-644-4216.

- E. **Vaccines:** Do not administer MMR or varicella vaccines for 5 months after administration of varicella vaccine or after 8 months after VZIG administered intravenously. The antibody in the immune globulin may interfere with the patient's immune system response.<sup>2,6</sup>

Varicella-zoster immune globulin does not interfere with a patient's response to typhoid, yellow fever, zoster, rotavirus or live flu vaccines.<sup>4</sup>

## 8. Other considerations

- A. **IGIV:** Patients receiving monthly high-dose ( $\geq 400$  mg/kg) immune globulin intravenous (IGIV) are likely to be protected and probably do not require VARIZIG® if the most recent dose of IGIV was administered  $\leq 3$  weeks before exposure.<sup>2</sup>
- B. **Repeat Dose of VARIZIG®:** Recommended for high-risk patients who have additional exposures to varicella virus  $\geq 3$  weeks after initial VARIZIG® administration, another dose of VARIZIG® should be considered.<sup>1,2</sup>
- C. **Altered Incubation with VARIZIG®:** Because VARIZIG® might prolong the incubation period by  $\geq 1$  week, any patient who receives VARIZIG® should be observed closely for signs and symptoms of varicella for 28 days after exposure.
- D. **Antiviral Use:** Antivirals should be instituted immediately should signs or symptoms of varicella occur.<sup>2</sup>
- E. **Nursing Mothers:** All classes of immunoglobulins can be detected in breast milk. Immunoglobulins from the mother help support the infant's health.<sup>5</sup>

## 9. Side effects and adverse reactions<sup>1</sup>

Adverse Event	Frequency
Injection site pain	3%
Headache	2%
Rash	1%
Fatigue	1%
Chills	1%
Nausea	1%

## 10. Storage and handling<sup>1</sup>

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 800-980-9431.

Vaccine	Temp	Storage Issues	Notes
VARIZIG®	2–8° C (36–46°F)	Do not freeze.	Do not use after expiration date.

## 11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table:

[https://vaers.hhs.gov/docs/VAERS\\_Table\\_of\\_Reportable\\_Events\\_Following\\_Vaccination.pdf](https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf)

Event and interval from vaccination
A. N/A

## 12. References

1. VARIZIG® Package insert 2018. Available at: [https://varizig.com/VARIZIG\\_PI.pdf](https://varizig.com/VARIZIG_PI.pdf). Accessed 08 Sept 2023.
2. CDC. Updated recommendations for the use of VARIZIG — United States, 2013. MMWR 2013;62;574–6. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6228a4.htm>. Accessed 08 Sept 2023.
3. CDC. Varicella. In: Epidemiology and Prevention of Vaccine-Preventable Diseases (“Pink Book”). Lopez A, Harrington T, Marin M, eds. 14th ed. Washington, DC: Public Health Foundation, 2021; 329–48. Available at: <https://www.cdc.gov/vaccines/pubs/pinkbook/varicella.html>. Accessed 08 Sept 2023.
4. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 2017. Available at: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf). Accessed 08 Sept 2023.
5. Cerini C, Aldrovandi G. Breast milk: proactive immunomodulation and mucosal protection against viruses and other pathogens. Future Virology 2013;8:(11). Available at: <https://www.futuremedicine.com/doi/abs/10.2217/fvl.13.91>. Accessed 08 Sept 2023.

6. DC. Appendix A-23 in: Epidemiology and Prevention of Vaccine-Preventable Diseases (“Pink Book”). Lopez A, Harrington T, Marin M, eds. 14th ed. Washington, DC: Public Health Foundation, 2021. Available at: <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/recommended-intervals-between-administration.pdf>. Accessed 01 Sept 2023.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 1-800-980-9431 and 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: [immunization protocol](#)

 Electronic copy of this pharmacy protocol is available at: [pharmacy protocols](#)